

## REMARKS

By the present amendment, Applicants' have currently amended Claim 1, and cancelled Claim 2. No new matter has been added to the claims. Claim 1 has been amended by incorporating the limitation of Claim 2. Claims 1 and 3-13 remain pending in the present application. Claims 1 and 13 are independent claims.

### Title

Examiner found the title to be not descriptive and suggested a new title. The new title has been incorporated into the specification.

### Rejection under 35 U.S.C. §102(b) as being anticipated by Shiao (US Pat. No. 5,201,779)

Examiner rejected claims 1, 3 and 5 as being anticipated by Shiao. Shiao discloses a disposable implant injector. The Examiner stated that Shiao comprised a hollow cylindrical barrel (10) wherein **“an injection tip of the barrel ha[s] elongated slots (11) extending from the injection end towards the filing end.”** Reference number 11 of Shiao are not “elongated slots (11)”, as characterized by the Examiner, instead, they are identified as twelve flaps 11. The flaps 11 are “multiple mutually separatable flaps which each expand outwardly when an implant ... is pressed against the flaps.” See abstract. Furthermore, the flaps 11 in Shiao, labeled as elongated slots (11) by the Examiner, do not extend from the injection end toward the filing end. The flaps 11 are disposed only at one end of the barrel 10 and they “form an injection tip”, col. 2, line 13. Even if flaps 11 of Shiao could be depicted as slots, the present breast implant injector invention, in light of amended claim 1, does not have a plurality of slots, but instead claims **“an elongated slot extending from the injection end to the opposing filling end.”**

Examiner described Shiao as disclosing “an injection end having a narrower diameter than the opposed filling end (Fig. 1a).” Though, the flaps (11) when they are all together and “not subject to any external force [...has a] smaller diameter”, see col. 2, lines 12-14, the flaps 11 will achieve “a sudden several-fold expanded diameter ...”, see col. 2, lines 28-30, when subject to pressure from a filled implant. As a result, when “the implant is passing through such injection tip each flap expands outwardly to enlarge the outlet...”, see col. 1, lines 37-39. Thus, the diameter of the injection tip in Shiao is not always truly narrower than the diameter of the opposing

end. The diameter of the injection tip in Shiao is conditionally narrow and can be as wide as the filling end, see Fig. 4 of Shiao and compare reference number 11 to reference number 10.

Furthermore, it is foreseeable that as the implant passes out the tip of the barrel 10 in Shiao, the flaps 11 when extended to a “several-fold expanded diameter” can flail and harmfully contact tissue and possibly inadvertently pierce, snag or poke the tissues within and around the incision point which may damage the already delicate surgical area. On the other hand, the present invention is a breast implant introducer that is designed to limit trauma to patient tissues especially in light of small incisions made in the body for the breast implant procedure. The guide cylinder 12 of the present invention is “relatively rigid and [does] not easily bend...”, see page 4 lines 19-20, and it “narrow[s] adjacent to the injection end 18 to improve the guidance of the [unfilled breast] implant 20 into the body cavity”, see page 4, lines 11-12.

Accordingly, Shiao does not disclose each and every limitation of the present claims and thus the 35 U.S.C. §102(b) anticipation rejection is improper. It is respectfully requested that the rejection of claims 1, 3 and 5 be withdrawn.

35 U.S.C. §103 rejection over Shiao in view of Shippert (US Pat. No. 5,507,807)

Examiner rejected claim 2 as being obvious over Shiao in view of Shippert. Though Shippert and Shiao are of the same art, there is no reason to combine Shippert with Shiao. Shiao is a disposable implant injector that ejects the implant through the tip of the injector past the multiple mutually separatable flaps. The Shippert invention does not eject substances from within the apparatus through an end tip as in the present invention or in Shiao. The Shippert invention “release[s] a contained substance along the length of the applicator when the applicator has been inserted and positioned in the patient.” See abstract. The Shippert invention is envisioned to have “the substance to be released ... be dispensed along a particular path...” See abstract. The Shippert invention cannot be reasonably combined with Shiao in that opposite the chamber opening 36 in the Shippert invention is a **closed** distal end 48 while in Shiao the distal injection end is open.

Even if Shippert could be combined with Shiao, the combination does not suggest the advantage of providing an opening for a fill tube of an unfilled implant as

in the present invention. Examiner cited Shippert for having an “opening in the side (32) of the assembly housing chamber, which can be of round cross-sectional shape (col 8, ln3), that runs the length of the housing from the filling to the injection end (col 6, ln 51-55) and is opened or closed by a side panel (76) to assist in containing the substance to be dispensed within the housing chamber ....” As stated above, the Shippert invention ejects substances from “along the length of the applicator.” Consequentially, Shippert’s “opening in the side 32” must be dimensioned and configured to permit such fluidic or solid substances to completely exit the applicator.

The slot 22 of the present invention is specifically designed so that a “fill tube 24 [on an unfilled implant can] extend out through the slot 22”, see p. 5, line12. “As the implant 20 is being pushed through the injection end 18, fill tube 24 is pushed along the elongated slot 22 until the fill tube passes out of elongated slot 22 at end 18. During passage of the implant through the guide cylinder 12, the fill tube 24 does not impede the passage of the implant 20 such as by folding under the implant as can happen if the elongated slot 22 were not present.” See page 6, line 11-16.

Neither Shippert nor Shiao suggest making use of the respective inventions for depositing an unfilled implant with a fill tube. Shiao makes reference of using the injector to deposit silicone implants having a specific volume, see background of Shiao, and Shippert discloses using the apparatus for injecting or releasing a fluidic or solid substance into a cavity or tissue of a patient but makes no reference of an implant that contains a fill tube. As above stated, the fill tube often impedes the passage of the implant through the prior art inventions.

Accordingly, the combination of Shiao with Shippert fails to render the present invention obvious. It is respectfully requested that the present rejection be withdrawn.

35 U.S.C. §103 rejection over Shiao in view of Kline (US Pat. No. 4,341,211)


Examiner found claim 4 obvious over Shiao in view of Kline. Kline is directed to a lubricating object applicator having has a gripping area 3, which the Examiner called an abutment. The gripping area 3 in Kline when combined with the invention of Shiao does not make the presently claimed invention obvious, in as much as the combined art fails to have an elongated slot extending from one end to an

opposite end of the body. It is respectfully requested that the rejection of claim 4 over the combination of Shiao and Shippert be withdrawn.

The Examiner's indication of allowable subject matter is noted with appreciation. Applicants are grateful for the allowance of claims 6-13. For at least these reasons, Applicant respectfully submits that independent amended Claim 1 and claims 3-13 are in condition for allowance. If such is not the case, the Examiner is requested to kindly contact the undersigned in an effort to satisfactorily conclude the prosecution of this application.

Respectfully submitted,

1/10/2006  
Date

  
Libby Babu  
Reg. No. 51,326

Frenkel & Associates  
3975 University Drive, Suite 330  
Fairfax, VA 22030  
Telephone (703) 246-9641  
Facsimile (703) 246-9646